

REMARKS

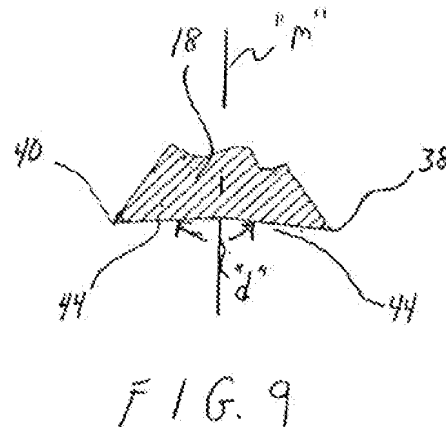
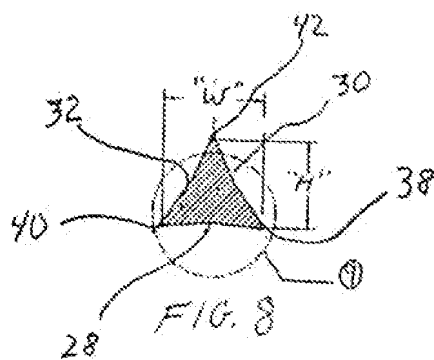
The above referenced application has been reviewed in light of the Final Office Action mailed July 21, 2010. Claims 1-9, 12, 14, 15, 20-22, 24 and 25 are currently pending in this application with claims 1 and 12 being in independent form. No amendments have been made to the claims herein. In view of the remarks to follow, reconsideration and allowance of this application are respectfully requested.

Claim Rejections - 35 U.S.C. §112

Claims 1-9, 12, 14, 15, 20-22, 24, and 25 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action states that the language "each side including one sole pair of planar surface portions" is considered new matter as it is not shown in the application. Applicants respectfully disagree.

As illustrated below in FIGS. 8 and 9, and described on page 8, lines 5-9 of the specification:

[E]ach surface 28, 30, 32 includes a pair of surface portions 44 which intersect at a large oblique angle "d" relative to each other. (FIG. 9) The preferred angle of intersection "d" ranges from about 160° to about 175°, most preferably 170°. The intersecting surface portions 44 thus provide an overall concave or hollow ground appearance to the respective surfaces 28, 30, 32. (Emphasis added.)



Thus, the claimed recitation of "each side including one sole pair of planar surface portions" is clearly described in Applicants' specification and shown in the figures. In view of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, of claims 1-9, 12, 14, 15, 20-22, 24, and 25 has been overcome and should be withdrawn.

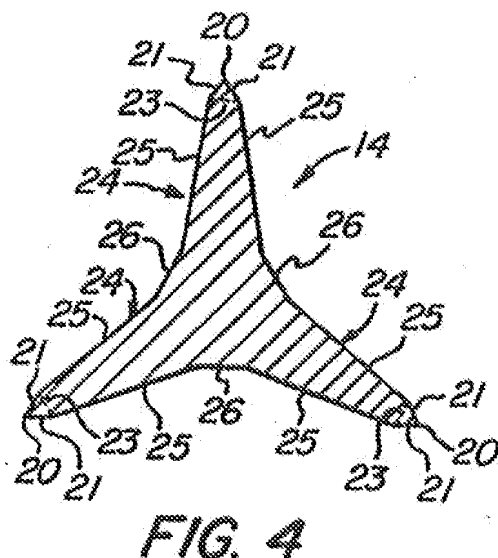
Claims Rejections - 35 U.S.C. §103(a)

Claims 1-9, 12, 14, 15, 20-22, 24, and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,403,344 to Allen ("Allen") in view of U.S. Patent No. 5,057,082 to Burchette, Jr. ("Burchette") and U.S. Patent No. 4,565,545 to Suzuki ("Suzuki"). Applicants respectfully submit that Allen, Burchette, and Suzuki, either alone or in combination, fail to teach or suggest the claimed surgical needle and that there is no reason, motivation, or suggestion in Allen, Burchette, or Suzuki to combine the references.

Claim 1 requires, *inter alia*, a "needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including *one sole*

pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side” (emphasis added).

As acknowledged in the Office Action, “Allen does not specify each side having one sole pair of planar surfaces.” Moreover, as illustrated in FIG. 4 of Allen, reproduced below, each side of Allen’s needle include *five* planar surface portions, i.e., reference numbers 21, 21, 25, 25, and 26. Allen states that the multi-faceted cross-section “provides improved penetration performance, less trauma and distortion and a reduced wound opening area.” (Allen at column 3, lines 58-60). Allen also provides that the needle head design provides for “significant reduction in stock removal necessary to sharpen the cutting edges 20, which results in less machining time and reduced manufacturing costs.” (Allen at column 3, lines 62-65).



In the Office Action, Burchette was relied on the teach “a cutting tip with each side having one sole pair of planar surfaces.” Burchette discloses a trocar assembly including a trocar tube and an obturator releasably supported within the trocar tube. The obturator includes an obturator end defined by three faces having a generally concave configuration. The Office Action asserts that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cross section of Burchette with the device of Allen, as this is appropriate in use for specific procedures and types of tissue.”

As described in Burchette, obturators are utilized “to puncture the walls of a body cavity for either draining fluid or for endoscopic procedures.” (Burchette at column 1, lines 9-11). Based upon the Office Action’s rationale, the cross section of Burchette is appropriate for such use, i.e., for puncturing the walls of body cavities for draining fluid or for endoscopic procedures. Nowhere is there any disclosure or suggestion that the obturator is appropriate for use as a surgical suture needle. Moreover, Allen teaches, with specificity, a multi-faceted cross-section to increase tissue penetration and needle sharpness of a surgical suturing needle. Accordingly, one would not look to combine Allen with Burchette and it is only with impermissible hindsight that any motivation for making a surgical needle having, among other things, “each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side” as recited in Claim 1.

In the Office Action, Suzuki was relied on to teach “the needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension “xt” of the enlarged transition portion” and “at least one side of the needled end portion being displaced by an angle alpha from a plane parallel to the longitudinal axis, the angle alpha being between about 2° and 10° wherein the side of the

needled end portion displaced by angle alpha from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point" (citations and parenthetical notations omitted).

Suzuki fails to cure the deficiencies of Allen and Burchette as Suzuki fails to teach a "needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side," as recited in Claim 1.

Additionally, there is no motivation to combine Allen with Suzuki. Suzuki discloses a catheter insertion device used for percutaneous insertion of a catheter into an artery or a vein located in a deep part of a tissue. The catheter insertion device includes an inner needle including a taper portion and a beveled surface at its distal end. The Office Action asserts that "it would have been obvious to one of ordinary skill in the art to use the geometry of Suzuki with the device of Allen, as the angle blade *increases the surface area* of the blade and aids in cutting the tissue" (emphasis added).

As stated above, however, the needle head of Allen is shaped so that the only portion that substantially contacts tissue during cutting is the three cutting edges to improve penetration performance, lessen tissue trauma and distortion, and reduce the wound opening area. Thus, increasing the surface area of Allen's needle, as suggested by the Office Action, is contrary to the teachings of Allen and would change the principle of operation of Allen.

According to §2143.01(VI) of the MPEP, the proposed modification cannot change the principle of operation of a reference -- "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being

modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 1 under 35 U.S.C. §103(a) over Allen in view of Burchette and Suzuki.

With regard to independent Claim 12, Claim 12 requires, *inter alia*, “each side including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side.”

In the Office Action, it was asserted that Allen discloses “each side including a pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side (Fig. 4).” Additionally, with respect to Claim 2, it was asserted that “Allen teaches the planar surface portions of each side are arranged to intersect along a median plan bisecting a respective side to define a substantially symmetrical concave appearance to the respective side.”

However, as shown with reference to FIG. 4 above, Allen fails to disclose this feature including a pair of planar surface portions that intersect along a median plane that bisects a respective side. Moreover, the Examiner has not articulated which features of Allen have been interpreted to be any of the claimed features.

Additionally, neither Burchette nor Suzuki discloses or suggests “each side including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side,” as recited in Claim 12. Moreover, Applicants maintain the arguments set forth above regarding the improper combination of Allen with Burchette and Suzuki.

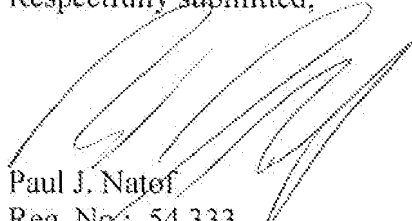
Thus, for at least these reasons, Applicants respectfully request withdrawal of the rejection of independent Claim 12 under 35 U.S.C. §103(a) over Allen in view of Burchette and Suzuki.

Since Claims 2-9, 22, and 24, which depend from Claim 1, and Claims 14, 15, 20, 21, and 25, which depend from Claim 12, contain all of the limitations of Claims 1 and 12, respectively, for at least the reasons presented above regarding the patentability of Claims 1 and 12, Applicants respectfully submit that the subject matter of each of Claims 2-9, 14, 15, 20-22, 24, and 25, as a whole, is also patentable over Allen, Burchette, and Suzuki.

In view of the foregoing remarks, Applicants submit that all of the claims are patentably distinct from the references of record and are in condition for allowance. The Examiner is invited to contact the undersigned Attorney at the telephone number listed below with any questions concerning this application.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.

Respectfully submitted,



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